


**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet,
film coated**

Elysium Pharmaceuticals Ltd

Diphenhydramine Hydrochloride

PRINCIPAL DISPLAY PANEL

<u>DIPHENHYDRAMINE HYDROCHLORIDE TABLETS 25 mg (PINK)</u>			
Each Film Coated Tablet Contains : Diphenhydramine Hydrochloride USP 25 mg			
Batch No. :	Shipper No. :	"S4" DEBOSSSED	
Mfg. Date :	Quantity : 1,00,000 Tablets		
Exp. Date :	NDC No. : 14803-273-00		
WARNING: KEEP OUT OF THE REACH OF CHILDREN		Manufactured By :	
STORE AT USP CONTROLLED ROOM TEMPERATURE OF 59° TO 86° F (15° TO 30° C) PROTECT FROM LIGHT, MOISTURE AND FREEZING.		 PHARMACEUTICALS LTD.	
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS THEREUNDER.		MANUFACTURER CODE No.: Guj/Drugs/G/1362 LABELER CODE # 14803	
CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"		Manufactured For : InvaTech Pharma Solutions LLC 40 C Cotters Lane, Suite # A, East Brunswick, NJ 08816 PH # 732-307-7926 FAX # 732-307-7931	

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14803-273
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
D&C RED NO. 17 (UNII: ND733RX3JN)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	S4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14803-273-00	100000 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/07/2024	

Labeler - Elysium Pharmaceuticals Ltd (915664486)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd.		915664486	manufacture(14803-273) , analysis(14803-273)